



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2021-0355; FRL-9565-01-OCSP]

#### Novaluron; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of novaluron in or on Almond, hulls and the Tree nut group 14-12. Makhteshim Agan of North America (ADAMA) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0355, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744.

Due to the public health concerns relating to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff

continues to provide customer service via email, phone, and webform. For the latest status information on EPA/DC services, docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Marietta Echeverria, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDfRNotices@epa.gov](mailto:RDfRNotices@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### *B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

#### *C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in

accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2021-0355 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2021-0355, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the *Federal Register* of June 28, 2021 (86 FR 33922) (FRL-10025-08) EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F8872) by Makhteshim Agan of North America, Inc. (d/b/a ADAMA), 3120 Highwoods Boulevard, Suite 100, Raleigh, NC 27604. The petition requested to establish tolerances for residues of the insecticide novaluron in or on Tree nuts, nutmeat (Crop Group 14-12) at 0.07 parts per million (ppm) and Almond, hulls at 15.0 ppm. That document referenced a summary of the petition, which is available in the docket, <https://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is establishing the tolerances at different levels than petitioned for and is modifying the crop group definition to be consistent with Agency terminology. A discussion of these modifications can be found in section IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for novaluron including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with novaluron follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings as well as an interim decision to support registration review for novaluron in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to novaluron and established tolerances for residues of that chemical. EPA is incorporating previously published sections from these rulemakings as described further in this rulemaking, as they remain unchanged.

*Toxicological profile.* For a discussion of the Toxicological Profile of novaluron, see Unit III.A. of the novaluron tolerance rulemaking published in the Federal Register of July 22, 2015 (80 FR 43329) (FRL-9929-57), which was not modified by the Novaluron Interim Registration Review Decision (<https://www.regulations.gov/document/EPA-HQ-OPP-2015-0171-0063>).

*Toxicological Points of Departure/Levels of Concern.* For a summary of the Toxicological Points of Departure/Levels of Concern for novaluron used for human risk

assessment, please reference Unit III.B. of the July 22, 2015, rulemaking as well as the Novaluron Interim Registration Review Decision.

*Exposure assessment.* EPA's dietary exposure assessments have been updated to include the additional exposure from the new uses of novaluron on the tree nut group 14-12 and almond hulls. An acute dietary exposure assessment was not performed as there are no appropriate toxicological effects attributable to a single exposure (dose). A partially refined chronic dietary (food and drinking water) exposure and risk assessment was conducted that incorporated tolerance-level residues for the proposed new uses. The chronic dietary exposure and risk assessment also incorporated average percent crop treated (PCT) data for several registered commodities. For the remaining commodities, 100 PCT was assumed. Anticipated residues for meat, milk, hog, and poultry commodities were incorporated as well. A cancer dietary assessment was not conducted because novaluron is classified as "not likely to be carcinogenic to humans."

*Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

Updated average percent crop treated values were used for the following crops that are currently registered for novaluron: apples (10%), broccoli (<1%), cabbage (5%), cantaloupe (<1%), cauliflower (<1%), cherries (<1%), cotton (5%), dry beans/peas (<1%), peaches (<1%), peanuts (5%), pears (25%), peppers (5%), plums/prunes (<1%), potatoes (5%), pumpkins (<1%), sorghum (<1%), squash (<1%), strawberries (45%), sugarcane (<1%), sweet corn (<1%), tomatoes (<2.5%), and watermelons (<1%).

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT

figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that Conditions a, b, and c discussed above have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which novaluron may be applied in a particular area.

*Drinking water and non-occupational exposures.* An updated drinking water assessment (DWA) for the proposed use of novaluron on tree nuts (Crop Group 14-12) was conducted. The maximum screening-level estimated drinking water concentrations (EDWCs) for uses on tree nuts are 9.6 ppb (acute) and 0.89 ppb (chronic) from surface water sources. The calculated EDWCs for these commodities do not supersede the previously used EDWCs of 31 ppb (acute) and 8.4 ppb (chronic). Therefore, the previously recommended EDWCs remain current and are considered protective potential drinking water residue levels anticipated from the proposed tolerance updates to tree nuts.



As stated in the August 13, 2020, rulemaking (85 FR 49261) (FRL-10011-78), the chronic dietary exposure and risk assessment incorporate the highest total EDWC of 8.4 parts per billion directly into this dietary assessment. The residential exposure assessment has not changed since the 2015 final rule because there are no proposed new residential uses. For a summary of the residential exposure analysis for novaluron used for the human risk assessment, please reference Unit III.C.3. of the July 22, 2015, rulemaking.

*Cumulative exposure.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to novaluron and any other substances and novaluron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that novaluron has a common mechanism of toxicity with other substances.

*Safety Factor for Infants and Children.* EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the July 22, 2015, rulemaking for a discussion of the Agency’s rationale for that determination.

*Aggregate risks and determination of safety.* EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer

risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

An acute dietary exposure assessment was not performed as there were no appropriate toxicological effects attributable to a single exposure (dose) observed in available oral toxicity studies, including maternal toxicity in the developmental toxicity studies. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 47% of the cPAD for children 1 to 2 years old, the group with the highest exposure. The combined short- and intermediate-term food, water, and residential exposures result in aggregate MOEs of 3,500 for adults and 250 for children 1 to 2 years old. These MOEs are greater than the level of concern of 100 and are therefore not of concern. Novaluron is classified as “Not Likely to Be Carcinogenic to Humans”; therefore, EPA does not expect novaluron exposures to pose an aggregate cancer risk.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to novaluron residues. More detailed information on this action can be found in the document titled “Novaluron. Human Health Risk Assessment for Proposed New Uses on Nut, Tree, Group 14-12” in docket ID EPA-HQ-OPP-2021-0355.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

For a discussion of the available analytical enforcement method, see Unit IV.A. of the July 22, 2015, rulemaking.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs)

established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

There are no Codex MRLs for either Almond, hulls or the Nut, tree, group 14-12 crop group; therefore, harmonization is not an issue.

### *C. Revisions to Petitioned-For Tolerances*

The Agency is establishing a 0.08 ppm tolerance level for Nut, tree, group 14-12, rather than at 0.07 ppm as proposed by the petitioner. The petitioner used the Organization for Economic Co-operation and Development (OECD) tolerance calculator but combined the almond and pecan data sets. EPA separately input the almond and pecan nutmeat data, which resulted in the higher residue. EPA is therefore using a tolerance level of 0.08 ppm (from almond data) as it is the higher of the two results. The commodity definition for “Tree nuts, nutmeat (Crop Group 14-12)” is also being modified to “Nut, tree, group 14-12” to be consistent with Agency nomenclature. EPA also revised the tolerance level for Almond, hulls to be consistent with the OECD rounding class practice.

## **V. Conclusion**

Therefore, tolerances are established for residues of novaluron in or on Almond, hulls at 15 ppm and the Nut, tree, group 14-12 at 0.08 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or to

Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 et seq.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

## **List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides, and pests, Reporting and recordkeeping requirements.

Dated: March 4, 2022.

**Marietta Echeverria,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

**PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Section 180.598(a) is amended by:

a. Adding a table heading; and

b. Adding the commodities “Almond, hulls” and “Nut, tree, group 14-12” to the table in alphabetical order.

The additions read as follows:

**§ 180.598 Novaluron; tolerances for residues.**

(a) \* \* \*

**Table 1 to Paragraph (a)**

Commodity	Parts per million
Almond, hulls	15
* * * * *	* *
Nut, tree, group 14-12	0.08
* * * * *	* *

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